Beta Bionics

A Massachusetts Public Benefit Corporation

Certified B Corporation

BETA BIONICS, INC.

ANNUAL REPORT
8 Saint Mary's Street
Boston, MA 02215-2421
www.betabionics.org

This Annual Report is dated May 1, 2017.

BACKGROUND INFORMATION

The Company[1], having offered and sold shares of its Class C Common Stock pursuant to Regulation CF under the Securities Act of 1933, is filing this annual report pursuant to Rule 202 of Regulation Crowdfunding (§227.202) for the fiscal year ended December 31, 2016. A copy of this report may be found on the Company's website at www.betabionics.org/about-us.

This report contains forward-looking statements and information relating to, among other things, the Company, its business plan and strategy, and its industry. These forward-looking statements are based on the beliefs of, assumptions made by, and information currently available to the Company's management. When used in the annual report, the words "estimate," "project," "believe," "anticipate," "intend," "expect" and similar expressions are intended to identify forward-looking statements, which constitute forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995.

The Company's forward-looking statements are based on management's current expectations and assumptions regarding the Company's business and performance, the economy and other future conditions and forecasts of future events, circumstances and results. As with any projection or forecast, forward-looking statements are inherently susceptible to uncertainty and changes in

[1] Throughout this report, Beta Bionics, Inc. is referred to as "the Company", "we," "us," or "our".

circumstances. The Company's actual results may vary materially from those expressed or implied in its forward-looking statements. Important factors that could cause the Company's actual results to differ materially from those in its forward-looking statements include government regulation, the Company's ability to raise additional capital, results of clinical trials, ability to achieve regulatory approval, economic, strategic, political and social conditions and the risk factors set forth herein.

Any forward-looking statement made by the Company speaks only as of the date on which it is made. The Company is under no obligation to, and expressly disclaims any obligation to, update or alter its forward-looking statements, whether as a result of new information, subsequent events or otherwise.

Name of issuer: Beta Bionics, Inc.
Legal status of issuer:
Form: Benefit Corporation
Jurisdiction of Incorporation/Organization: Massachusetts
Date of organization: October 21, 2015
Physical address of issuer:
Business Innovation Center – Photonics Center, Mail Stop 936 / Office: Suite 614, 8 Saint Mary's Street, Boston, MA 02215-2421
Website of issuer: www.betabionics.org

DIRECTORS, EXECUTIVE OFFICERS AND SIGNIFICANT EMPLOYEES

The Company's officers and board of directors are identified in the following tables.

Officers of the Company

Name	Principal Occupation	Hire date	Term of Office
Edward R. Damiano	Founder, Chief Executive Officer and President	1-1-16	Indefinite
Gibb Clarke	VP, Chief Financial Officer & Treasurer	1-1-16	Indefinite
Firas El-Khatib	VP, Autonomous Systems	1-1-16	Indefinite
Edward B. Raskin	VP, Public Benefit Development & Corporate Strategy	1-1-16	Indefinite
Serafina Raskin	VP, General Counsel and Corporate Secretary	1-1-16	Indefinite
Mike Rosinko	VP, Research & Development	1-3-17	Indefinite

Directors of the Company

Director	Principal Occupation	Main Employer(s)	Year Joined as Director
Edward R. Damiano	CEO of Beta Bionics & Professor of Biomechanical Engineering	Beta Bionics, Inc. and Boston University	2015
Edward B. Raskin	Attorney and VP, Public Benefit Development & Corporate Strategy	Beta Bionics, Inc.	2015
Jeff Hitchcock	President, Children with Diabetes	Children With Diabetes	2016
Deirdre Ibsen	Global Brand Development Leader, Lilly Diabetes	Eli Lilly and Company	2016
Martin Holst Lange, M.D., PhD	Corporate Project Vice President, Insulin & Devices, Global Development, Novo Nordisk	Novo Nordisk A/S	2017

Edward R. Damiano, PhD, President, CEO & Board Director

Ed Damiano is a Professor of Biomedical Engineering at Boston University and has held that role since 2004. His expertise and training are in the areas of mechanical and biomedical engineering and applied mechanics. Ever since his now 17-year-old son David was diagnosed with type 1 diabetes at 11 months of age, he has been committed to creating and integrating closed-loop control technologies with a vision of building a bionic pancreas by the time his son heads off to college. This endeavor began with the design and development of mathematical control algorithms for blood glucose control, which he and his team began testing in his laboratory at Boston University in 2005 and has led to the development of the iLet bionic pancreas system. In 2015, Ed and Firas El-Khatib founded Beta Bionics, Inc. as a Massachusetts public benefit corporation with the goal of bringing the iLet through final clinical trials, regulatory approval and into the hands of people with type 1 diabetes.

Gilbert Clarke, MBA, VP, Chief Financial Officer and Chief Operations Officer

Gibb Clarke is a serial entrepreneur who has launched several successful medical device companies and is intimately familiar with the many challenges and opportunities ahead for the Company. At Beta Bionics, Gibb applies his 15 years of leadership experience in the medical device field to help the Company optimize and realize its revenue potential by streamlining operations, managing suppliers and Company finances. In addition to his role at Beta Bionics Gibb is the Chief Executive Officer of Three Rivers Medical—a position he has held since 2015. From 2011 to 2014 Gibb was the Chief Executive Officer of Blockade Medical LLC. Gibb holds a Masters in Business Administration degree from Duke University.

Firas El-Khatib, PhD, VP, Autonomous Systems

In addition to his role at Beta Bionics, Firas El-Khatib is a co-investigator and a senior research scientist in the Department of Biomedical Engineering at Boston University, a role he has held since 2006. Firas created the control algorithms that run the insulin-only, glucagon-only and bi-hormonal configurations of the iLet bionic pancreas. At Beta Bionics, Firas directs and supports algorithm implementation and clinical research efforts with clinical partners to develop data necessary to gain regulatory approval of the iLet.

Jeff Hitchcock, Board Director

Jeff Hitchcock is the Founder and President of Children with Diabetes, an Ohio-based 501(c)(3) non-profit that provides education and support to families living with type 1 diabetes through its web site (www.childrenwithdiabetes.com) and conferences throughout the United States and in Canada and the United Kingdom. Since founding Children with Diabetes in 1995, Jeff and Children with Diabetes have hosted countless conferences and educational events focused on improving the lives of families living with diabetes.

Deirdre Ibsen, Board Director

Deirdre Ibsen has been an employee of Eli Lilly and Company for over 25 years. Since 2011 she has served as the Global Brand Development Leader for Insulin and Devices in the Diabetes Business Unit based in Indianapolis, Indiana. Deidre has been a director of the Beta Bionics' Board since January 2016.

Martin Holst Lange, M.D., PhD, Board Director

Martin Lange is a long-term employee of Novo Nordisk A/S. Since 2013, he has worked as Corporate Project Vice President for Insulin & Devices. Martin is the newest director of the Beta Bionics Board and brings a wealth of knowledge in the diabetes market to the Board.

Edward Raskin, JD, VP Public Benefit Development & Corporate Strategy, Board Member

In addition to his role as a Vice President and director on the Beta Bionics Board, Ed Raskin is also a partner in Kassinove & Raskin LLP, which he founded with Dr. Andrew Kassinove, MD/JD in 2009, to defend and advise companies in the healthcare industry. At Beta Bionics, Ed is responsible for developing and aligning the company's business goals and objectives with its public benefit structure, social mission and B Corp certification. In addition, he helps

implement strategies for maximizing collaboration and relationships with strategic business partners and investors around the world. Ed's son Max was diagnosed with type 1 diabetes at the age of 7.

Serafina Raskin, JD, VP, General Counsel and Corporate Secretary
In addition to her role as General Counsel and Corporate Secretary for Beta Bionics, Serafina Raskin is a partner with Kassinove & Raskin LLP where she has worked since 2011. In her private practice, Serafina leads a team of attorneys who serve hospital systems, physicians' groups, long-term care organizations and other healthcare providers and payers. She works with clients on regulatory and compliance matters, medical staff and licensing issues, contract negotiations, litigation and general corporate law. She brings extensive experience in the management of legal affairs and compliance in the health-care field. She is admitted to practice law in California and registered as general counsel with the Massachusetts Bar. Her son, Max, was diagnosed with T1D in 2013 and is the impetus for her work at Beta Bionics and community service for type 1 diabetes organizations like the ADA.

Michael Rosinko, VP of Research and Development
Mike Rosinko joined Beta Bionics from Tandem Diabetes, where he was the Director of Research & Development since 2008. Mike carried the T:Slim and other Tandem produces from ,inception to commercialization, until his departure to join Beta Bionics. At Tandem he was responsible for project management, product development, engineering management, design controls and risk analysis. Not only does Mike bring over 25 years of experience in the medical device field to Beta Bionics, he also brings with him the specialized knowledge necessary to gain regulatory approval and commercialize a novel pumping platform. Mike holds a Masters of Business Administration from Claremont Graduate University, a Masters of Science in Electrical Engineering from the University of Southern California, and a Bachelors of Science in Electrical Engineering from University of Pittsburgh, where he graduated cum laude. In addition, he holds 10 patents in medical systems and devices.

CAPITAL STRUCTURE

The Company's securities

The total number of shares of all classes of stock which the Company has authority to issue is (i) 1,000,000 shares of Class A Common Stock, (ii) 1,000,000 shares of Class B Common Stock, (iii) 500,000 shares of Class C Common Stock, (iv) 99,000 shares of Series A Preferred Stock, (v) 99,000 shares of Series A-2 Preferred Stock and (vi) 301,000 shares of undesignated Preferred Stock.

The respective rights of each class of stock, as provided in the Company's Third Amended and Restated Bylaws, are outlined in the following table:

Class of Security	Securities (or Amount) Authorized	Securities (or Amount) Outstanding	Voting Rights	Other Rights
Preferred Stock (list each class in order of preference):				
• Series A Preferred Stock & Series A-2 Preferred Stock	99,000 (Series A) 99,000 (Series A-2)	50,000 50,000	Yes @ one vote per share as converted to Class B Common Stock	• Dividend rights, senior to Common A and B • Liquidation preference • Conversion rights • Anti-dilution protections • Registration rights • Information rights, including access to clinical trial results and form factor testing data • Access to prototype and working models of the product • Pre-emptive rights • Rights of first refusal (Series A); Right of second refusal (Series A-2)/co-sale on sales by other shareholders • No redemption rights • 1 seat on the Company's Board of Directors • 1 seat any scientific, technical, or clinical advisory committees

Common Stock				
• Class A Common Stock	1,000,000	600,000	Yes @ ten votes per share	None
• Class B Common Stock	1,000,000	250,000	Yes @ one vote per share	None
• Class C Common Stock	500,000	9,691	No voting rights	None
Debt Securities	None	None	None	None
Other	None	None	None	None

Class of Security	**Securities Reserved for Issuance upon Exercise or Conversion**
Warrants	None
Options	100,000 Class B Common Stock (Employee Incentive Option Pool)
Other rights:	None

As indicated in the table above, the rights of Class C Common Stock are materially limited by the rights held by the Series A Preferred Stock, Series A-2 Preferred Stock, Class A Common Stock, and Class B Common Stock. Unlike other classes of the Company's stock, Class C Common Stock offers no special rights or preferences, no priority to dividend rights, no voting rights, no rights to a seat on the Company's Board of Directors or other scientific, technical or advisory committees, no right to purchase additional shares to preserve equity ownership in the Company in the event that the Company later conducts another round of financing, no special informational rights, no special ability to exercise control over management decisions of the Company and no liquidity to protect against downside risks.

Additionally, no holder of Class C Common Stock may sell, transfer, assign, pledge or otherwise dispose of or encumber any Class C Common Stock without the Company's prior written

consent. The Company may withhold consent for any legitimate corporate purpose and to generally limit incremental costs associated with administering such transfers.

Principal Security Holders
The following table sets out the Company's voting securities that are owned by holders of more than 20% of the Company's voting securities, as of December 31, 2016.

	Number and Class of Securities Held			
Shareholder	**Class A Common Stock**	**Class B Common Stock**	**Class C Common Stock**	**% of Voting Power**
Edward Damiano and Toby Milgrome	600,000	-	-	94.49%
Firas El-Khatib	-	200,000	-	3.15%

The above calculation is the number of shares of voting securities owned as of December 31, 2016. Note that Class A Common Stock possesses a 10:1 voting power over Class B Common Stock. Class C Common Stock is non-voting. Series A and A-2 Preferred Stock convert to Class B Common Stock.

Risks associated with being a minority shareholder

As holders of a majority-in-interest of voting rights in the Company, Edward R. Damiano and Toby Milgrome may make decisions with which the other investors disagree, or that negatively affect the value of other investors' securities in the Company, and the other investors will have no recourse to change these decisions. Other investors' interests may conflict with those of the majority shareholders, and there is no guarantee that the Company will develop in a way that is optimal for or advantageous to the minority shareholders.

For example, Edward R. Damiano and Toby Milgrome may: change the management of the Company; vote to engage in new offerings and/or to register certain of the Company's securities in a way that negatively affects the value of the securities owned by minority investors; or even force out minority holders of securities.

Other holders of securities of the Company may also have access to more information than the minority investors, leaving the minority investors at a disadvantage with respect to any decisions regarding the securities they own. For example, as part of the investor agreement with Eli Lilly & Company and Novo Nordisk A/S, a representative of the each has a seat on the Company's Board of Directors and has rights to review certain Company records. The Trustee's of Boston University (BU) hold similar rights to review certain Company records of the Company and a BU representative has the right to observe all Board meetings.

Risks associated with additional issuances of securities and dilution

The Company will likely sell interests to additional investors, which would dilute the percentage interest held by minority shareholders. This means that the pro-rata portion of the Company represented by the minority investor's securities will decrease, which could also diminish the minority shareholders' economic rights. Minority shareholders may have the opportunity to increase their investment in the Company in such a transaction, but such opportunity cannot be assured. The amount of additional financing needed by the Company will depend upon the maturity and objectives of the Company.

In cases where the rights of holders of outstanding options or warrants are exercised, or if new awards are granted under our equity compensation plans, minority holders' interests in the Company may also be diluted. In addition, as discussed above, if a majority-in-interest of holders of securities with voting rights cause the Company to issue additional stock, the minority shareholders' interest will typically also be diluted.

Based on the risks described above, minority shareholders could lose all or part of their investment and may never see positive returns.

Risks related to the valuation of the Company's securities

As a private company, valuing our security is a difficult task. Unlike public companies that actively trade stock in the public marketplace, there is no public market for Beta Bionics equity and there are no revenues to evaluate and inform any valuation.

In the future, we anticipate that we will perform valuations of the various classes of our stock that take into account factors such as the following:

- unrelated third party valuations of our common stock;
- the price at which we sell other securities, such as convertible debt or preferred stock, in light of the rights, preferences and privileges of our those securities relative to those of our common stock;
- our results of operations, financial position and capital resources;
- current business conditions and projections;
- the lack of marketability of our common stock;
- the hiring of key personnel and the experience of our management;
- the introduction of new products;
- the risk inherent in the development and expansion of our products;
- our stage of development and material risks related to our business;
- the likelihood of achieving a liquidity event, such as an initial public offering or a sale of our company given the prevailing market conditions and the nature and history of our business;
- industry trends and competitive environment;
- trends in consumer spending, including consumer confidence;

- overall economic indicators, including gross domestic product, employment, inflation and interest rates; and
- the general economic outlook.

We will analyze factors such as those described above using a combination of financial and market-based methodologies to determine our business enterprise value. For example, we may use methodologies that assume that businesses operating in the same industry will share similar characteristics and that the Company's value will correlate to those characteristics, and/or methodologies that compare transactions in similar securities issued by us that were conducted in the market. We underscore that the value of the Company's shares can decrease by actions taken by the Company's management or by forces outside of management's control.

Limited transferability and liquidity

Conditions imposed by securities laws and regulations must be satisfied prior to any sale, transfer, conversion or other disposition of our common stock. There is no established public trading market for the resale of our Common Stock, specifically our Class C Common Stock which was sold via Regulation CF. Our investors should assume that they may not be able to liquidate their investment for some time, if ever.

Risks associated with a sale of the issuer or of assets of the issuer

Minority non-voting owners of the Company's stock will have no ability to influence a potential sale of the Company or a substantial portion of its assets. Thus, they rely upon the executive management of the Company, the Board of Directors of the Company, and the Company's existing voting shareholders to manage the Company and to realize value for shareholders.

Accordingly, the success of minority shareholders' investment in the Company will depend in large part upon the skill, expertise and decisions of the executive management of the Company, the Board of Directors of the Company and the voting shareholders of the Company. If the Board of Directors of the Company authorizes a sale of all or a part of the Company, or a disposition of a substantial portion of the Company's assets, there can be no guarantee that the value the minority shareholders will receive, together with the fair market estimate of the value remaining in the Company, will be equal to or exceed the value of the minority shareholders' investment in the Company.

Transfer agent and registrar

eShares, Inc., 195 Page Mill Road, Suite 01, Palo Alto, CA 94306 is the transfer agent and registrar for the Company's common stock.

DESCRIPTION OF BUSINESS AND BUSINESS PLAN

A. Overview

Beta Bionics is a development stage biotechnology company developing a bionic pancreas system called the iLet™, a revolutionary fully integrated and wearable bionic pancreas medical device platform that automatically and autonomously manages blood sugar levels in people with type 1 insulin-dependent diabetes (T1D) 24/7, and thus reduces the burden and cost of diabetes care. Good, consistent management of blood sugar levels in people with T1D is essential to preventing and minimizing health complications but consistent management is oppressive – requiring the kind of vigilance that is unsustainable and impossible for many. What makes it different from all other diabetes medical devices that have come before it is that the iLet offers a holistic, fully automated systems approach to glycemic control, rather than just providing a component technology that addresses only one part of the glycemic control challenge (e.g. insulin infusion, glucose sensing, therapeutic dosing decisions, etc.).

The iLet integrates: (1) a glucose-sensing device that automatically and frequently estimates blood sugar levels; (2) decision software that automatically determines therapeutic dosing requirements; and (3) a single-hormone and dual-hormone configuration that automatically delivers insulin to lower blood sugar levels and glucagon (in the case of the dual-hormone system) to raise blood sugar levels. The iLet is designed to solve the four greatest concerns of T1D management: (1) it reduces mean glycemia in nearly everyone to levels that would meet or exceed the American Diabetes Association's goal for therapy, and would likely nearly eradicate long-term microvascular and neurological complications if implemented at the time of diagnosis; (2) it profoundly curtails mild hypoglycemia in everyone, and we expect it to dramatically reduce the risk of severe hypoglycemia; (3) it automates glycemic management, thus unburdening people with T1D of the relentless need to comply with therapy, as the bionic pancreas itself is the first technology to be entirely compliant with the patient's needs rather than the other way around; and (4) it unburdens people with T1D and their families of the emotional hardship that is, for now, part of everyday life, and of the constant fear of hypoglycemia, and of the worry and dread of long-term complications. A device that solves any one of these concerns would be groundbreaking; a device that simultaneously solves all four is without precedent and truly game changing.

No Basal. No Bolus. Just Go
… Go Bionic!©

Not only is our technology innovative, but so too is our corporate structure. Our Company was formed on October 21, 2015 as a Massachusetts public benefit corporation, which is a relatively new corporate structure that allows, and, in fact, obliges, private companies to consider general and specific public benefit in its management decisions, in addition to considering the traditional corporate goals of maximizing profit for shareholders.

Our bylaws establish the following four principles to guide us in the specific public benefit of improving human health for the T1D community:

1. To provide and to protect our turnkey solutions for safe and effective autonomous glycemic control;
2. To bring our technology to as many people with T1D as possible in an expeditious and responsible manner;
3. To continue to innovate and to offer the latest advances as expeditiously and responsibly as possible; and
4. To act in the best possible interest of the T1D community in connection with fulfilling our functions.

Since our incorporation, our primary activities have been the development of our business plan, negotiating strategic alliances and other agreements, and raising capital. In the first two-and-a-half months of our existence, we successfully negotiated and licensed the intellectual property related to the bionic pancreas technology from Boston University.

These foundational steps allow the Company to ultimately seek regulatory approval and, if achieved, commercialize the iLet. Information related to the iLet is preliminary and investigative. The iLet is not yet approved by the U.S. Food and Drug Administration (FDA). Regulatory approval of the iLet is critical to our success and ensuring that we meet our public benefit mission. To date, we have not generated any revenues from our operations and do not expect to do so in the near future.

B. Labor of Love

Dr. Edward R. Damiano, a Boston University professor of biomedical engineering, and senior research scientist Firas El-Khatib (at that time a student working with Ed in his lab) began their quest to develop a portable bionic pancreas not long after Ed's son, David, was diagnosed with T1D as an infant by his wife, Toby – a pediatrician. Managing David's blood sugar perfectly proved impossible, and the consequences of not being perfect can be extremely dangerous, and even acutely life threatening. Despite meticulous attention to detail, it was clear that David, himself, changed from day to day and even hour to hour, such that decisions made under seemingly identical circumstances the day before would have different outcomes the next day. The child grows, comes down sick, feels content or anxious, eats all of his food or doesn't, has a different mix of carbs, fats, and proteins in one meal compared to another, plays hard that day or doesn't, or the dose of insulin given is off by just a little bit. The result is a child who is fine, or hypoglycemic, combative or helpless, or hyperglycemic and heading to a lifetime of disability, including blindness, organ failure, and amputations. Furthermore, there is a tremendous amount of biological activity and hormonal variability from night to night, making blood sugar control a 24-hour-a-day, seven-day-a-week task.

Convinced that there should be a better solution to the management of insulin-dependent diabetes, Ed and his team embarked upon a journey to unburden himself, his son and so many parents, children and adults living with the burden of diabetes.

Ultimately, the entire team at Beta Bionics is deeply motivated to bring the iLet to someone they love and care for. It is a labor of love for all of us. We are building this for the T1D community – a community to which we all belong.

C. Market

Diabetes is a chronic, life-threatening disease for which there is no known cure. Diabetes is caused by the body's inability to produce or effectively utilize insulin, a life-sustaining hormone, to regulate the body's glucose levels.

In people with diabetes, blood glucose levels fluctuate from extremely high levels, a condition known as hyperglycemia, which is caused by too little insulin, to extremely low levels, a condition called hypoglycemia, which is caused by too much insulin.

Hyperglycemia may cause the individual with diabetes to feel thirsty or confused, but it can also be insidious and not noticed at all. However, it is not benign and over years, hyperglycemia causes devastating damage to the body, including damaging small blood vessels which leads to blindness, nerve damage and kidney failure, and also damaging larger blood vessels, which leads to coronary artery disease, stroke, heart attack, poor wound healing and amputation of the distal extremities. In its most severe form, hyperglycemia with ketosis (diabetic ketoacidosis) will cause death in a matter of hours to days without intervention. Medical management of acute DKA is itself risky, and deaths can occur from acute shifts in electrolytes and fluids.

All of this can be avoided by giving insulin, but the problem is that too much insulin leads to hypoglycemia, which causes confusion, combative irrational behavior, shakiness, feeling of extreme stress due to catecholamine release, loss of mental acuity, unconsciousness, seizure, coma and death.

The current state of the art for diabetes management has not proven adequate to balance the dangers of hyper- and hypoglycemia, although millions of people are compelled to try, day in and day out, with varying degrees of success.

We are profoundly grateful for the tools we do have, because without them our loved ones might not be alive today. However, soon we will all be able to do much better with less work and worry, with the iLet.

There are two main types of diabetes: type 1 (T1D) and type 2 (T2D).

- T1D is caused by an autoimmune response in which the body attacks and destroys the insulin-producing cells in the pancreas, called beta cells—hence the "Beta" in the name of our company. As a result, the pancreas' ability to produce insulin is almost entirely destroyed. T1D is most commonly diagnosed during childhood or adolescence, but adults may also develop T1D. According to estimates, between 1.5 and as many as 3 million Americans may have type 1 diabetes.

- T2D is caused by increasing resistance to the insulin produced by the beta cells. T2D has been most commonly thought of as a disease of middle and advanced age, but it is increasingly prevalent in children and adolescents. Over 29 million Americans have T2D (9.3% of the population) and 14% of those individuals need insulin.

D. Current Treatment Options

Currently, there is no system that autonomously makes all therapeutic decisions to administer insulin (or insulin and glucagon) in response to a continuous signal from a continuous glucose monitor ("CGM") has been FDA-approved or is commercially available. The current state-of-the-art in the management of T1D includes:

- The regular use of hand-held, in vitro blood glucose meters (BGM). These meters are capable of measuring the glucose concentration of small blood samples (~ 0.3-5 µl) in 5-30 seconds; the capillary blood sample is obtained by pricking the skin with a lancet,

- The use of rapid-acting human insulin analogs that can be adjusted to compensate for meals rather than making meal adjustments to match the insulin taken hours earlier, and, finally,

- Insulin pumps that can continuously deliver subcutaneous insulin at an infusion rate to suit metabolic insulin requirements, and by microburst infusion of insulin to treat carbohydrates consumed through user commanded dosing.

- An insulin pump paired with a continuous glucose monitor that operates in a "hybrid closed loop" configuration. This system, known as the Minimed 670G, was approved by the FDA on September 29, 2016 and as of December 31, 2016 was not yet widely available in the marketplace, if at all. Commercial availability is expected in "Spring 2017" according to publicly available information found at https://www.medtronicdiabetes.com/products/minimed-670g-insulin-pump-system. The 670G has an "Auto Mode**"** option that, under certain circumstances, automatically adjusts basal insulin delivery every 5 minutes based on blood glucose levels.

Although the key to managing diabetes is to maintain tight control of blood glucose levels, in practice, the management of T1D is extremely challenging, requiring perpetual vigilance and intervention with insulin or carbohydrates. Without a doubt, the iLet's automated insulin and glucagon administration would materially reduce the burden associated with managing the disease.

E. More About the iLet

The iLet is a wearable stand-alone Class III medical device intended to provide ambulatory autonomous care for insulin-dependent diabetes. The iLet consists of:

1. an integrated dual-chamber pump capable of delivering insulin alone or insulin and glucagon at microprecise doses and an integrated touchscreen user interface;

2. an integrated CGM;

3. a clinically tested suite of mathematical control algorithms that autonomously determine and command doses of insulin or glucagon based on CGM glucose data; and

4. a custom dual-cannula infusion set.

The iLet requires only the patient's weight for initialization and then autonomously adapts in real-time to changes in an individual's basal metabolic insulin need, acute (e.g. circadian hormonal fluctuations, intercurrent illness, physical activity, or emotional state), or gradual (e.g. hormonal changes that occur during puberty or menopause). Our adaptive meal dose controller eliminates the need for the user to set or know their "carbohydrate-to-insulin ratios", as it makes automatic adjustments based on dosing history for similar past meal announcements, and customizes its doses to the individual and time of day. The bihormonal configuration of our iLet also includes a proportional-derivative algorithm (based on the glucose level and rate of descent) governing subcutaneous micro-doses of glucagon to help prevent or reduce hypoglycemia beyond the capability of our insulin-only configuration.

Taken together, these mathematical algorithms provide a universal framework for a glycemic control strategy that requires no quantitative input from, or participation by, the user (besides entering body weight to initialize the iLet), but which automatically adapts insulin and glucagon dosing to meet each individual's needs. Another challenge we overcame is enabling our iLet to remain autonomous in managing insulin and glucagon delivery even when the CGM is offline by: (1) invoking the latest high-resolution "basal rate profile" it had converged upon when the CGM was online, (2) responding to meal announcements the same way, and (3) automatically responding to user-entered BG values by issuing a correction dose of insulin (or glucagon) based on its latest determination of the user's needs. Thus, our iLet never relies on, nor burdens the user, with determining subjective dosing decisions, which inevitably vary in quality and reliability over time or among different users. Indeed, our iLet provides a turnkey solution for people with T1D that comprehensively manages glycemia across a broad range of individual needs and a large spectrum of circumstances and challenges.

In summary, the iLet's technology is pioneering because it:

- It is initialized only with the patient's body mass and comes online immediately with no run-in period;
- It provides a truly turnkey solution for both children and adults with T1D, and is able to cope with a wide range of insulin needs across all age groups.
- It uses no more insulin than under usual care, but distributes insulin doses more efficiently and optimally than under usual care, and thus dramatically improves mean glycemia and reduces hypoglycemia.
- It is designed to specifically refrain from stacking and overdosing insulin.
- It is completely autonomous in determining all dose deliveries, sparing the user to ever have to determine or set their so-called "basal-rate profiles", "correction factors", or "insulin-to-carbohydrate ratios".

- It continuously updates and stores a high-resolution "basal-rate" profile for insulin delivery (288 basal rate segments per day), which it dynamically adapts when the CGM is online, and automatically invokes when the CGM is offline.
- It autonomously doses insulin or glucagon for high or low glucose levels when the CGM is online and automatically corrects as necessary by dosing insulin or glucagon in response to user-entered BG values when the CGM is offline.
- It allows optional user-initiated (but system-calculated) meal-priming insulin doses, which adapt autonomously to user requirements and time of day (separately for "breakfast", "lunch", and "dinner" meals).
- It automatically shuts off insulin dosing, based on the glucose level and its trend, to prevent hypoglycemia.
- It allows the user to run a system-optimized dynamic glucose target or to set a permanent glucose target, or to temporarily raise the glucose target for added safety during activities such as exercising, driving, etc.
- It allows the user to trigger a (system-calculated) glucagon microburst dose, as an added safety measure prior to temporarily disconnecting from the BP, such as for showering, swimming, etc.
- It has been tested in C-peptide-negative as well as C-peptide-positive subjects in the outpatient setting.
- It has been tested under free-living conditions and without restrictions on exercise or other activities.

F. Licenses, Patents and Proprietary Rights

We have exclusive, worldwide sub-licensable licenses from the Trustee's of Boston University (BU) to a portfolio of U.S. and international patents (both issued and pending) and a trademark that relate to iLet.

Under the terms of the licensing agreements, we are responsible for specified milestone and maintenance payments, as well as royalty payments on net sales once commercialized. We also have the right to sublicense our rights under the license agreements but are required to pay a percentage of any sublicense income.

Additionally, under the terms of the licensing agreements, we must develop, manufacture, sell and market the technology pursuant to specified milestones and time schedule. In the event we fail to meet the milestones, BU is entitled to terminate the licensing agreements with prior written notice, provided we do not cure the breach. Upon termination, the intellectual property under the licenses would revert back to BU.

We believe that proprietary protection of our technologies is critical to the development of our business. Our intellectual property strategy includes protecting existing, and further developing, proprietary technology for the sourcing, scale up, and manufacturing of the iLet. This strategy includes expanding on technologies in-licensed to us as well as in-licensing additional technologies through collaborations with universities and biotech companies.

We rely upon trade-secret protection for certain confidential and proprietary information and take active measures to control access to that information. There is also substantial proprietary know-how surrounding the iLet development and manufacturing processes that remains a trade secret. We currently have confidentiality and non-disclosure agreements with all of our employees, consultants, vendors, advisory board members and contract research organizations.

G. Our Commitment to Good Business Practices and Our Public Benefit Mission

We benefit the public by providing education, support and eventually the bionic pancreas technology to alleviate the burdens of T1D management. We believe our status as a public benefit corporation, commitment to our public benefit mission, and focus on transparency, makes all the difference in the way we do business. We believe this will result in a healthier and happier T1D community.

Where other companies may focus only on return on investment, we are committed both to our shareholders and to the T1D community and will work diligently to ensure that the bionic pancreas technology is protected and available for your benefit. Beta Bionics is actively involved in the T1D community and is partnering with like-minded educational institutions, not-for-profit entities and socially minded companies to educate the public about T1D management and our bionic pancreas technology.

Our leadership strives to be ever mindful that it was founded by parents deeply affected by T1D to help not only their children, but all children and adults struggling to live with T1D and their loved ones who support them.

H. Performance of the Bionic Pancreas System in Trials

The bionic pancreas technology has been rigorously tested in inpatient and real-world outpatient and home-use studies in subjects with T1D in both the insulin-only and bihormonal configurations. The technology has evolved over the years from a laptop-driven system, to the first wearable iPhone-driven platform, to our current highly compact, fully integrated, mobile iLet.

A nine-year collaboration between Boston University (BU) and the Massachusetts General Hospital (MGH), resulted in 3 inpatient studies testing a laptop version of the bihormonal bionic pancreas in adults and adolescents with T1D in the clinical research center at MGH.

The iPhone version of the bihormonal bionic pancreas has also been tested in 4 outpatient studies. Although still somewhat cumbersome, the iPhone system was a mobile platform that could be tested in home-use environments, afforded unrestricted subject activity, and allowed for longer-duration experiments than was previously possible.

In 2013, the iPhone system was tested in five-day experiments in 20 adults with T1D in downtown Boston (the Beacon Hill Study). The Summer 2013 and 2014 studies, compared the iPhone system with insulin pump therapy in 5-day experiments in 51 children 6 to 20 years old

with T1D at Camp Joslin and the Clara Barton Camp in central Massachusetts (the 2013 and 2014 Summer Camp Studies).

A collaboration between MGH, the University of Massachusetts Medical Center, Stanford University, and the University of North Carolina, Chapel Hill, resulted in the Bionic Pancreas Multicenter Study between 2014 and 2015, and compared the iPhone system with insulin pump therapy in a home-use study in 39 adults with T1D who used the device for 11 days at work and at home.

The mean CGM glucose levels obtained by the bihormonal bionic pancreas from the 2013 and 2014 Summer Camp Studies and the Bionic Pancreas Multicenter Study, were 141 ± 10 mg/dl in adults, 142 ± 12 mg/dl, in adolescents, and 137 ± 11 mg/dl in pre-adolescents. Based on these mean CGM glucose levels, we are able to project what the bionic pancreas is capable of achieving in terms of HbA1c in the three populations of ~ 6.5 ± 0.4%.

It is important to note that the bionic pancreas was able to achieve mean CGM glucose levels below the American Diabetes Association (ADA) goal for therapy in all three populations in nearly all subjects tested while simultaneously eliminating almost all hypoglycemia. On the bionic pancreas, CGM glucose levels fell below 60 mg/dl only 0.6% of the time in adults and 1.2–1.3% of the time in adolescents and pre-adolescents in a summer camp setting.

Our clinical collaborators at Stanford and at MGH have also conducted two home-use outpatient studies testing the iPhone-based bionic pancreas system in the insulin-only configuration and targeting different glycemic set-points. In the study conducted by the Stanford team, 16 adults with T1D compared the bionic pancreas in the insulin-only configuration with insulin pump therapy in one-week experiments at work and at home (with a glucose target of 130 mg/dl). In the study conducted by the MGH team, 20 adults with T1D compared our bionic pancreas in the insulin-only configuration at a set-point of 130 mg/dl, with the bionic pancreas in the bihormonal configuration at glucose set-points of 100, 115, and 130 mg/dl, and with insulin pump therapy in 3-day experiments at work and at home.

The mean CGM glucose levels obtained by the insulin-only bionic pancreas with a glycemic set-point of 130 mg/dl was 161 ± 9 mg/dl in the Stanford Insulin-only Study and 160 ± 17 mg/dl in our MGH Set-Point Study, with CGM glucose levels falling below 60 mg/dl only 0.9% and 0.8% of the time, respectively. Based on these mean CGM glucose levels, we project that our insulin-only bionic pancreas would achieve an HbA1c in adults of 7.2 ± 0.5%, while simultaneously limiting CGM glucose levels below 60 mg/dl to less than 1% of the time.

Thus, we project that the insulin-only configuration of our bionic pancreas would result in HbA1c levels of ~ 7.3%. The bionic pancreas in the bihormonal configuration would obtain HbA1c of ~ 6.5%, which would effectively eradicate all long-term complications of T1D.

The academic team has also tested the first generation of our fully integrated iLet bionic pancreas in diabetic swine. Notably, results of the swine study showed no difference in the performance of our previous-generation iPhone-based bionic pancreas platform relative our iLet platform.

Despite challenging conditions, and no restrictions on diet, exercise and activity, the previous generations of the bionic pancreas technology have simultaneously lowered mean glucose and reduced hypoglycemia relative to comparator groups and demonstrated that the current iteration of the technology is ready to withstand the rigors of a Pivotal Trial.

I. Published Clinical Data Related to the Bionic Pancreas Technology

For purposes of non-scientific summary, the following clinical data has been published by the academic team according to peer-review standards in the following highly regarded journals:

- The Lancet, 2016:
  - Background: The safety and effectiveness of a continuous, day-and-night automated glycemic control system using insulin and glucagon has not been shown in a free-living, home-use setting. We aimed to assess whether a bihormonal bionic pancreas initialized only with body mass can safely reduce mean glycemia and hypoglycemia in adults with type 1 diabetes who were living at home and participating in their normal daily routines without restrictions on diet or physical activity.
  - Methods: We conducted a random-order crossover study in volunteers at least 18 years old who had type 1 diabetes and lived within a 30 minute drive of four clinical sites in the US. Participants were randomly assigned (1:1) in blocks of two using sequentially numbered sealed envelopes to a bihormonal bionic pancreas or usual care (conventional or sensor-augmented insulin pump therapy) first, followed by the opposite intervention. Both study periods were 11 days in length, during which time participants continued all normal activities, including athletic activities and driving. The bionic pancreas was initialized with only the participant's body mass. Autonomously adaptive dosing algorithms used data from a continuous glucose monitor to control subcutaneous delivery of insulin and glucagon. The coprimary outcomes were the mean glucose concentration and time with continuous glucose monitoring (CGM) glucose concentration less than 3·3 mmol/L, analyzed over days 2–11 in participants who completed both periods of the study. This trial is registered with ClinicalTrials.gov, number NCT02092220.
  - Results: We randomly assigned 43 participants between May 6, 2014, and July 3, 2015, 39 of whom completed the study: 20 who were assigned to bionic pancreas first and 19 who were assigned to the comparator first. The mean CGM glucose concentration was 7·8 mmol/L (SD 0·6) during the bionic pancreas period versus 9·0 mmol/L (1·6) during the comparator period (difference 1·1 mmol/L, 95% CI 0·7–1·6; p<0·0001), and the mean time with CGM glucose concentration < 3·3 mmol/L was 0·6% (0·6) during the bionic pancreas period versus 1·9% (1·7) during the comparator period (difference 1·3%, 95% CI 0·8–1·8; p<0·0001). The mean nausea score on the Visual Analogue Scale (score 0–10) was greater during the bionic pancreas period (0·52 [SD 0·83]) than during the comparator period (0·05 [0·17]; difference 0·47, 95% CI 0·21–0·73; p=0·0024). Body mass

and laboratory parameters did not differ between periods. There were no serious or unexpected adverse events during the bionic pancreas period of the study.

- The Lancet Diabetes and Endocrinology, 2016:
  - Background: The safety and efficacy of continuous, multiday, automated glycemic management has not been tested in outpatient studies of pre-adolescent children with type 1 diabetes. We aimed to compare the safety and efficacy of a bihormonal bionic pancreas versus conventional insulin pump therapy in this population of patients in an outpatient setting.
  - Methods: In this randomized, open-label, crossover study, we enrolled pre-adolescent children (aged 6–11 years) with type 1 diabetes (diagnosed for ≥1 year) who were on insulin pump therapy, from two diabetes camps in the USA. With the use of sealed envelopes, participants were randomly assigned in blocks of two to either 5 days with the bionic pancreas or conventional insulin pump therapy (control) as the first intervention, followed by a 3-day washout period and then 5 days with the other intervention. Study allocation was not masked. The autonomously adaptive algorithm of the bionic pancreas received data from a continuous glucose monitoring (CGM) device to control subcutaneous delivery of insulin and glucagon. Conventional insulin pump therapy was administered by the camp physicians and other clinical staff in accordance with their established protocols; participants also wore a CGM device during the control period. The coprimary outcomes, analyzed by intention to treat, were mean CGM-measured glucose concentration and the proportion of time with a CGM-measured glucose concentration below 3.3 mmol/L, on days 2–5. This study is registered with ClinicalTrials.gov, number NCT02105324.
  - Results: Between July 20, and Aug 19, 2014, 19 children with a mean age of 9.8 years (SD 1.6) participated in and completed the study. The bionic pancreas period was associated with a lower mean CGM-measured glucose concentration on days 2–5 than was the control period (7.6 mmol/L [SD 0.6] *vs* 9.3 mmol/L [1.7]; p=0.00037) and a lower proportion of time with a CGM-measured glucose concentration below 3.3 mmol/L on days 2–5 (1.2% [SD 1.1] *vs* 2.8% [1.2]; p<0.0001). The median number of carbohydrate interventions given per participant for hypoglycemia on days 1–5 (ie, glucose <3.9 mmol/L) was lower during the bionic pancreas period than during the control period (three [range 0–8] *vs* five [0–14]; p=0.037). No episodes of severe hypoglycemia were recorded. Medium-to-large concentrations of ketones (range 0.6–3.6 mmol/dL) were reported on seven occasions in five participants during the control period and on no occasion during the bionic pancreas period (p=0.063).

- The New England Journal of Medicine, 2014:

- Background**:** The safety and effectiveness of automated glycemic management have not been tested in multiday studies under unrestricted outpatient conditions.
- Methods**:** In two random-order, crossover studies with similar but distinct designs, we compared glycemic control with a wearable, bihormonal, automated, "bionic" pancreas (bionic-pancreas period) with glycemic control with an insulin pump (control period) for 5 days in 20 adults and 32 adolescents with type 1 diabetes mellitus. The automatically adaptive algorithm of the bionic pancreas received data from a continuous glucose monitor to control subcutaneous delivery of insulin and glucagon.
- Results: Among the adults, the mean plasma glucose level over the 5-day bionic-pancreas period was 138 mg per deciliter (7.7 mmol per liter), and the mean percentage of time with a low glucose level (<70 mg per deciliter [3.9 mmol per liter]) was 4.8%. After 1 day of automatic adaptation by the bionic pancreas, the mean (±SD) glucose level on continuous monitoring was lower than the mean level during the control period (133±13 vs. 159±30 mg per deciliter [7.4±0.7 vs. 8.8±1.7 mmol per liter], P<0.001) and the percentage of time with a low glucose reading was lower (4.1% vs. 7.3%, P=0.01). Among the adolescents, the mean plasma glucose level was also lower during the bionic-pancreas period than during the control period (138±18 vs. 157±27 mg per deciliter [7.7±1.0 vs. 8.7±1.5 mmol per liter], P=0.004), but the percentage of time with a low plasma glucose reading was similar during the two periods (6.1% and 7.6%, respectively; P=0.23). The mean frequency of interventions for hypoglycemia among the adolescents was lower during the bionic-pancreas period than during the control period (one per 1.6 days vs. one per 0.8 days, P<0.001).

- Journal of Clinical Endocrinology and Metabolism, 2014:
  - Background**:** The objectives of the study were to test the ability of a third-generation bihormonal bionic pancreas algorithm, initialized with only subject weight, to adapt automatically to the different insulin needs of adults and adolescents, and to evaluate the impact of optional, automatically adaptive meal-priming boluses.
  - Methods: This was a randomized controlled trial, conducted at an inpatient clinical research center with twelve adults and twelve adolescents with T1D. Subjects in each age group were randomized to automated glycemic control for 48 hours with or without automatically adaptive meal-priming boluses.
  - Results: The 48-hour mean PG values with and without adaptive meal-priming boluses were 132.9 vs 146.9 mg/dL (*P* .03) in adults and 162.6 vs 175.9 mg/dL (*P* .01) in adolescents. Adaptive meal-priming boluses improved mean PG without increasing time spent with PG less than 60 mg/dL: 1.4% vs 2.3% (*P* .6) in adults and 0.1% vs 0.1% (*P* 1.0) in adolescents. Large increases in adaptive meal-priming boluses and shifts in the timing and size of automatic insulin doses occurred in adolescents.

Much less adaptation occurred in adults. There was nearly a 4-fold variation in the total daily insulin dose across all cohorts (0.36 –1.41 U/kg/d).

- Diabetes Care, 2012:
  - Background: To test whether safe and effective glycemic control could be achieved in type 1 diabetes using a bihormonal bionic endocrine pancreas driven by a continuous glucose monitor in experiments lasting more than two days and including six high-carbohydrate meals and exercise as challenges to glycemic control.
  - Methods: Six subjects with type 1 diabetes and no endogenous insulin secretion participated in two 51-h experiments. Blood glucose was managed with a bionic endocrine pancreas controlling subcutaneous delivery of insulin and glucagon with insulin pumps. A partial meal-priming bolus of insulin (0.035 units/kg/meal, then 0.05 units/kg/meal in repeat experiments) was administered at the beginning of each meal (on average 78 ± 12 g of carbohydrates per meal were consumed). Plasma glucose (PG) control was evaluated with a reference quality measurement on venous blood every 15 min.
  - Results: The overall mean PG was 158 mg/dL, with 68% of PG values in the range of 70–180 mg/dL. There were no significant differences in mean PG between larger and smaller meal-priming bolus experiments. Hypoglycemia (PG,70 mg/dL) was rare, with eight incidents during 576-h of closed-loop control (0.7% of total time). During 192-h of nighttime control, mean PG was 123 mg/dL, with 93% of PG values in the range of 70–180 mg/dL and only one episode of mild hypoglycemia (minimum PG 62 mg/dL).

- Science Translational Medicine, 2010
  - Background: Automated control of blood glucose (BG) concentration is a long-sought goal for type 1 diabetes therapy. We have developed a closed-loop control system that uses frequent measurements of BG concentration along with subcutaneous delivery of both the fast-acting insulin analog lispro and glucagon (to imitate normal physiology) as directed by a computer algorithm. The algorithm responded only to BG concentrations and incorporated a pharmacokinetic model for lispro.
  - Methods: Eleven subjects with type 1 diabetes and no endogenous insulin secretion were studied in 27-hour experiments, which included three carbohydrate-rich meals.
  - Results: In six subjects, the closed- loop system achieved a mean BG concentration of 140 mg/dl, which is below the mean BG concentration target of <_154 mg/dl recommended by the American Diabetes Association. There were no instances of treatment- requiring hypoglycemia. Five other subjects exhibited hypoglycemia that required treatment; however, these individuals had slower lispro absorption kinetics than the six subjects that did not become hypoglycemic. The time-to-peak

plasma lispro concentrations of subjects that exhibited hypoglycemia ranged from 71 to 191 min (mean, 117 ± 48 min) versus 56 to 72 min (mean, 64 ± 6 min) in the group that did not become hypoglycemic (aggregate mean of 84 min versus 31 min longer than the algorithm's assumption of 33 min, P = 0.07). In an additional set of experiments, adjustment of the algorithm's pharmacokinetic parameters (time-to-peak plasma lispro concentration set to 65 min) prevented hypoglycemia in both groups while achieving an aggregate mean BG concentration of 164 mg/dl. These results demonstrate the feasibility of safe BG control by a bihormonal artificial endocrine pancreas.

In addition to the above, the academic bionic pancreas team has published multiple additional manuscripts on their pre-clinical studies, commentaries and other manuscripts related to blood glucose control and continuous glucose monitoring studies. Clinical data related to bionic pancreas multi-center study, during which subjects wore the system from eleven days to three weeks has been collected but not yet formally published. The data collected from those studies continues to show that the bionic pancreas system effectively lowers mean average blood glucose while simultaneously reducing hypoglycemia and substantially eases the psychological burdens of managing T1D.

All prior published clinical data is available online at:
http://sites.bu.edu/bionicpancreas/publications-2/.

J. The Pivotal Trial and Development Status

Our goal is to work with our clinical teams to initialize the Bihormonal Bionic Pancreas Pivotal Trial ("Pivotal Trial"), in the middle of 2019 assuming successful completion of a phase II.B bihormonal bridging study scheduled for 1st quarter 2018. Final trial design protocol is subject to change and is not in final format. However, as proposed as of December 31, 2016, we plan to enroll at least 600 subjects with T1D in three age groups (≥ 18 (at least 1/3 greater than 50 years old), 12-17, and 4-11 staging enrollment in younger subjects as safety is demonstrated). Our goal is to test and qualify the iLet and to provide all of the clinical data necessary for a pre-market approval (PMA) application to the FDA for the bihormonal configuration of the device. Separately, our goal is to work with our clinical teams to initialize the Insulin-Only Bionic Pancreas Pivotal Trial in the middle of 2018 assuming successful completion of an insulin-only bridging study scheduled for the second half of 2017.

We propose to achieve this objective with the following two specific aims:

1. to conduct the insulin-only pivotal trial (which we expect will take up to 11 months to complete) in order to test the safety and efficacy of the iLet in controlling glycemia in the insulin-only configuration and to evaluate the behavioral and psychosocial impact of the insulin-only configuration of the iLet relative to usual care,
2. to conduct the bihormonal Pivotal Trial (which we expect to take 15 months or more to complete), in order to test the safety and efficacy of the iLet in controlling glycemia in the bihormonal configuration, to evaluate the behavioral and psychosocial impact of the

bihormonal configuration of the iLet relative to usual care, and to provide all safety data necessary and sufficient for a new chronic use indication for glucagon in this device.

Our ability to commence the bihormonal Pivotal Trial and the insulin-only Pivotal Trial depends on securing FDA and IRB approvals for the trial and securing necessary funding, as well as completing shorter bridging studies to demonstrate feasibility of the fully integrated iLet to autonomously control blood glucose.

As of December 31, 2016, existing resources are not adequate to permit us to ensure that the bihormonal Pivotal Trial or the insulin-only Pivotal Trial is completed. In addition to one or more additional financings and grants, a funding request submitted through BU to the National Institutes of Health, if funded, is expected to cover substantially all current projected costs of running the bihormonal Pivotal Trial, or, potentially the insulin-only Pivotal Trial. We are continuing to explore potential opportunities and alternatives to obtain additional resources that may be necessary to complete the planned bihormonal Pivotal Trial, insulin only Pivotal Trial, and to support our operations in the interim. These opportunities and alternatives may include partnering arrangements with biotech or pharmaceutical companies. There can be no assurance that we will secure any grants, or that any such financings or partnering arrangements can be consummated on acceptable terms, if at all.

The bihormonal Pivotal Trial and insulin-only Pivotal Trial we have designed will provide the essential clinical data necessary for a PMA submission for the iLet – a technology that will forever change the way in which T1D is managed and the effectiveness with which that care can be delivered as well as treat other conditions of glycemic impairment such as type 2 diabetes, post-bariatric surgery induced hypoglycemia, congenital hyperinsulinism, and insulinoma induced chronic hypoglycemia.

K. Manufacturing of the iLet

We do not have manufacturing facilities adequate to produce the iLet within Beta Bionics. We currently rely, and expect to continue to rely, on third-party contract manufacturers for the manufacture of the iLet in the short term. The iLet, is being built and manufactured as a Class III medical device by an FDA-registered ISO 13485 third-party contract manufacturing facility. The dual-cannula infusion set is being built and manufactured by a third-party facility that is fully compliant with relevant CFR 21, cGMP, ISO manufacturing protocols, and FDA standards. Eventually, we may decide to establish in-house manufacturing capabilities.

L. Sales and Marketing

We may choose to partner with large biotech or pharmaceutical companies for sales and marketing, if and when applicable, or alternatively develop our own sales force to market the iLet both inside and outside of the U.S. If we obtain CE Mark for the iLet, we anticipate initiating sales in the European market as well.

M. Collaboration Arrangements

From time to time we will enter into collaborative research agreements with academic and research institutions, including BU, to enhance our research and development capabilities. Typically, in industry, such agreements provide the industry partner with rights to license the intellectual property created through such collaborations. We may also enter into collaborative research agreements with other pharmaceutical companies when we believe such collaboration will support the development and commercialization of our technology.

N. Sublicenses to Third Parties

We currently do not have any sublicenses with third parties but we may, in the future decide to grant sublicenses for certain applications of our technologies.

O. Future Products/Indications for Use

Eventually, we may decide to seek an indication for use in type 2 diabetes who require daily insulin therapy as well as those suffering from glycemic impairment. There is also a potential for in-hospital use of our technology.

NUMBER OF CURRENT EMPLOYEES

As of the date of this report, the Company's total employee count is 16. Additionally, we engage a number of independent contractors to perform various services for the Company. Among the contractors we employ are regulatory consultants, contract manufacturers, engineering and design consultants, attorneys and accountants, just to name a few. As we expand our operations we anticipate hiring additional personnel and engaging additional contractors.

RISK FACTORS

Risks Related to our Intellectual Property and Potential Litigation

We do not own the intellectual property underlying the iLet.

We rely on licenses from the Trustees of Boston University to use the various technologies that are material to operation of the iLet. We do not own the patents that underlie these licenses. The first license grants us exclusive worldwide rights under the five patents and one copyright related to the control algorithm run by the iLet. The second license grants us exclusive worldwide rights related to five patents relating to the infusion sets which deliver subcutaneously the glucagon and insulin hormones. Our rights to use these technologies and employ the inventions claimed in the licensed patents are subject to our abiding by the terms of the licenses and meeting certain milestones set forth in the applicable license agreements. In addition, while we have significant input and participation into the strategy for the enforcement of the patent and trademark rights, the Trustees of Boston University has the ultimate control over the prosecution and enforcement strategies relating to the patents and trademarks subject to these licenses. As a result, we are largely dependent upon the Trustees of Boston University determine the appropriate strategy for prosecuting and enforcing the rights to the intellectual property under the license agreements.

Our ability to protect our intellectual property and proprietary technology is uncertain.

We rely on our trademarks and trade names to distinguish our products from the products of our competitors, and have registered or applied to register many of these trademarks. We cannot assure you that our trademark applications will be approved in a timely manner or at all. Third-parties also may oppose our trademark applications, or otherwise challenge our use of the trademarks. In the event that our trademarks are successfully challenged, we could be forced to rebrand our products, which could result in loss of brand recognition, and could require us to devote additional resources to marketing new brands. Further, we cannot assure you that competitors will not infringe upon our trademarks, or that we will have adequate resources to enforce our trademarks.

We have entered into confidentiality agreements and intellectual property assignment agreements with our officers, employees, temporary employees and consultants regarding our intellectual property and proprietary technology. In the event of unauthorized use or disclosure or other breaches of those agreements, we may not be provided with meaningful protection for our trade secrets or other proprietary information.

If a competitor infringes upon one of our patents, trademarks or other intellectual property rights, enforcing those patents, trademarks and other rights may be difficult and time consuming. Patent law relating to the scope of claims in the industry in which we operate is subject to rapid change and constant evolution and, consequently, patent positions in our industry can be uncertain. Even if successful, litigation to defend our patents and trademarks against challenges or to enforce our intellectual property rights could be expensive and time consuming and could divert management's attention from managing our business. Moreover, we may not have sufficient resources or desire to defend our patents or trademarks against challenges or to enforce our intellectual property rights. Litigation also puts our patents at risk of being invalidated or interpreted narrowly and our patent applications at risk of not issuing. Additionally, we may provoke third-parties to assert claims against us. We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded, if any, may not be commercially valuable. The occurrence of any of these events may have a material adverse effect on our business, financial condition and operating results.

The medical device industry is characterized by patent litigation, and we could become subject to litigation that could be costly, result in the diversion of management's time and efforts, or require us to pay damages.

Our success will depend in part on not infringing the patents or violating the other proprietary rights of third-parties. Significant litigation regarding patent rights exists in our industry. Our competitors in both the United States and abroad, many of which have substantially greater resources and have made substantial investments in competing technologies, may have applied for or obtained or may in the future apply for and obtain, patents that will prevent, limit or otherwise interfere with our ability to make and sell our products. The large number of patents, the rapid rate of new patent issuances, and the complexities of the technology involved increase the risk of patent litigation.

In the future, we could receive communications from various industry participants alleging our infringement of their intellectual property rights. Any potential intellectual property litigation could force us to do one or more of the following:

- stop selling our products or using technology that contains the allegedly infringing intellectual property;
- incur significant legal expenses;
- pay substantial damages to the party whose intellectual property rights we are allegedly infringing;
- redesign those products that contain the allegedly infringing intellectual property; or
- attempt to obtain a license to the relevant intellectual property from third-parties, which may not be available on reasonable terms or at all.

Any litigation or claim against us, even those without merit, may cause us to incur substantial costs, and could place a significant strain on our financial resources, divert the attention of management from our core business and harm our reputation. Further, as the number of participants in the diabetes market increases, the possibility of intellectual property infringement claims against us increases.

We may be subject to damages resulting from claims that we, or our employees, have wrongfully used or disclosed alleged trade secrets of our competitors or are in breach of non-competition or non-solicitation agreements with our competitors.

We may be subject to claims that we, or our employees, have inadvertently or otherwise used or disclosed trade secrets or other proprietary information of these former employers or competitors. In addition, we have been and may in the future be subject to allegations that we caused an employee to breach the terms of his or her non-competition or non-solicitation agreement. Litigation may be necessary to defend against these claims. Even if we successfully defend against these claims, litigation could cause us to incur substantial costs, and could place a significant strain on our financial resources, divert the attention of management from our core business and harm our reputation. If our defense to those claims fails, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. We cannot guarantee that this type of litigation will not continue, and any future litigation or the threat thereof may adversely affect our ability to hire additional direct sales representatives. A loss of key personnel or their work product could hamper or prevent our ability to commercialize proposed products, which could have an adverse effect on our business, financial condition and operating results.

Risks Related to Our Legal and Regulatory Environment

If we or our third-party suppliers violate the FDA's good manufacturing practice regulations, our ability to market our product in a cost-effective and timely manner will be impaired.

If we should obtain marketing approval for our product, such product, along with the manufacturing processes, post-approval clinical data and promotional activities for the product, would be subject to continual review and inspections by the FDA and other regulatory agencies. Under the FDA's medical device reporting ("MDR") regulations, we must report to the FDA any

incident in which our product may have caused or contributed to a death or serious injury. Further, under the MDR, we must report any incident in which our product malfunctioned in such a manner that, if the malfunction were to recur, it would likely cause or contribute to a death or serious injury. Finally, we and our third-party suppliers must comply with the FDA's Quality System Regulation ("QSR"), and other regulations, which address the methods and documentation of the design, testing, production, control, quality assurance, labeling, packaging, sterilization, storage and shipping of our products. The FDA enforces compliance with the QSR through announced and unannounced inspections of manufacturing and other facilities, conducted at periodic intervals.

We do not presently have our own manufacturing facilities; however, if, in the future, we acquire manufacturing facilities, we will seek the FDA's approval of the facility for medical device manufacturing and report the results of the FDA's inspection of the facility. We cannot assure you that we will acquire manufacturing facilities or that we will be able to obtain FDA or other regulatory approval of such facilities.

If our suppliers or we fail to comply with the applicable regulatory requirements in any serious respect, or if, in response to any observed deficiencies, we propose a corrective action plan that is deemed insufficient, the FDA could take enforcement action against us. Enforcement action could include any of the following measures: warning letters; fines and civil penalties; unanticipated expenditures; delays in approving or refusal to approve our continuous glucose monitoring systems; withdrawal of approval by the FDA or other regulatory bodies; product recall or seizure; interruption of production; operating restrictions; injunctions; and criminal prosecution. Any such action could have a material adverse impact on our reputation, business, financial condition and operating results. If we or our suppliers have significant non-compliance issues, or if any corrective action plan that we or our suppliers propose in response to observed deficiencies is not sufficient, the FDA could take enforcement action against us. Any of the foregoing actions could have a material adverse effect on our reputation, business, financial condition and operating results.

Even if regulatory approval of a product is granted, the approval may be subject to limitations on the indicated uses for which the product may be marketed or contain requirements for costly post-marketing testing and surveillance to monitor the safety or efficacy of the product. If problems with our product are later discovered, including software bugs, the occurrence of unanticipated adverse events, manufacturing problems, or the failure to comply with regulatory requirements such as the QSR, such problems may result in restrictions on the product or manufacturing processes, withdrawal of the product from the market, voluntary or mandatory recalls, fines, suspension of regulatory approvals, product seizures, injunctions, or the imposition of civil or criminal penalties.

Recall of our product, or the discovery of safety issues with our product, could have a significant negative impact on us.

If the FDA determines that our product shows material deficiencies or defects in design or manufacture, or poses an unacceptable risk to health, the FDA has the authority to require the recall of our product. Manufacturers may also recall a product if they find any material deficiency in the product. In the event our product is associated with an unacceptable risk to health, component failures, manufacturing errors, design or labeling defects or other deficiencies,

a government-mandated or voluntary recall by us, or one of our distributors, could occur. If our product were recalled, such recall would divert managerial and financial resources and have an adverse effect on our reputation, financial condition and operating results. These results could impair our ability to produce the product in a cost-effective and timely manner.

Further, under the FDA's medical device reporting ("MDR") regulations, we must report to the FDA any incident in which our product may have caused or contributed to a death or serious injury, or in which our product malfunctioned in such a manner that, if the malfunction were to recur, it would likely cause or contribute to a death or serious injury. If the product were to malfunction repeatedly, voluntary or involuntary product recall could result. Such a result could divert managerial and financial resources, impair our ability to manufacture our product in a cost-effective and timely manner, and have an adverse effect on our reputation, financial condition and operating results.

Any adverse event involving our product could result in future voluntary corrective actions, such as recalls or customer notifications, or regulatory agency action, which could include inspection, mandatory recall or other enforcement action. If we are required to take corrective action, such action, whether voluntary or involuntary, will require the dedication of our time and capital, distract management from operating our business, and may harm our reputation and financial results.

If we fail to comply with the extensive government regulations affecting us, our business will suffer.

Governmental authorities – principally the FDA and various state regulatory agencies – regulate the medical device industry extensively. The regulations are complex and are subject to rapid evolution and varying interpretations. Regulatory restrictions or changes could limit our ability to conduct or expand our operations, or could result in higher than anticipated costs or lower than anticipated sales. The FDA and other U.S. governmental agencies regulate numerous elements of our business, including product design and development; pre-clinical and clinical testing and trials; product safety; establishment registration and product listing; labeling and storage; marketing, speech/statements regarding the iLet, manufacturing, sales and distribution; pre-market clearance or approval; servicing and post-market surveillance; advertising and promotion; and recalls and field safety corrective actions.

Before we can market or sell a new regulated product or a significant modification to an existing product in the United States, we must obtain either approval under Section 510(k) of the FDCA or approval of a pre-market approval ("PMA") application from the FDA. As a Class III medical device that we must comply with the PMA approval process and demonstrate the safety and effectiveness of the product on the basis of extensive data. The PMA process is customarily required for products that are deemed to pose the greatest risk, such as life-sustaining, life-supporting or implantable devices. If a product is approved through a PMA application process, the product generally needs FDA approval before it can be modified. The process of obtaining regulatory approvals to market a medical device can be costly and time-consuming, and we may not be able to obtain these approvals on a timely basis, or at all, for our proposed product.

If the FDA requires us to conduct a more rigorous examination for future products or modifications to our existing product than we had expected, we could be delayed in, or prevented from, introducing our product or modifications. A delay or cancellation could cause our sales to

decline or not to increase in accord with our forecasts. In addition, the FDA may determine that future iterations of our product will require the more costly, lengthy and uncertain PMA process.

The FDA can delay, limit or deny approval of a product for many reasons, including our inability to demonstrate that our product is safe and effective for its intended use; the insufficiency of our clinical trials data to support approval; and the failure of our manufacturing process or facilities to meet applicable requirements.

In addition, the FDA may change its clearance and approval policies, adopt additional regulations or revise existing regulations, or take other actions which may prevent or delay approval of our product. Such actions by the FDA could also impact our ability to modify our currently approved product on a timely basis.

If we experience any delay in obtaining approval for our product, or any failure to maintain approval for our product, such circumstances could prevent us from generating revenue from the product or achieving profitability. In addition, the FDA and other regulatory authorities have broad enforcement powers. Regulatory enforcement or inquiries, or other increased scrutiny on us, could cause customers not to use our product and could negatively impact our reputation and the perceived safety and efficacy of our product.

If we fail to comply with applicable regulations, such failure could jeopardize our ability to sell our product and result in enforcement actions such as fines, civil penalties, injunctions, warning letters, recalls of products, delays in the introduction of products into the market, refusal of the FDA or other regulators to grant future approvals, and the suspension or withdrawal of existing approvals by the FDA or other regulators. If we were to incur any of these sanctions, we could experience higher than anticipated costs or lower than anticipated sales. As a result, the sanctions could have a material adverse effect on our reputation, business, financial condition and operating results.

Further, we may consider international expansion opportunities in the future. If we expand our operations outside of the United States, we will become subject to various additional regulatory and legal requirements under the applicable laws and regulations of the international markets. These additional regulatory requirements may involve significant costs and, if we are not able to comply with any such requirements, our international expansion and business could be significantly harmed.

The healthcare industry is subject to extensive federal, state and local laws and regulations relating to billing for services; financial relationships with physicians and other referral sources; inducements and courtesies given to patients; quality of medical equipment and services; confidentiality, maintenance and security issues associated with medical records and individually identifiable health information; medical device reporting; false claims; professional licensure; and labeling products. These laws and regulations are complex and, in some cases, still evolving. In many instances, these laws and regulations have not received significant regulatory or judicial interpretation. If our operations are found to violate any of the federal, state or local laws and regulations which govern our activities, we may be subject to the penalty associated with the violation. Such penalties could include civil and criminal penalties, damages, fines or curtailment of our operations. Since many of these laws and regulations have not been fully interpreted by the regulatory authorities or the courts, we face an increased risk that we could be

found in violation of such laws and regulations. Even if we successfully defend an action against us for violation of these laws or regulations, the defense could cause us to incur significant legal expenses and divert our management's time and attention from the operation of our business.

In addition, healthcare laws and regulations may change significantly in the future. Any such change may adversely affect our business. A court's or regulatory agency's review of our business may result in a determination that could adversely affect our operations. Also, the healthcare regulatory environment may change in a manner that restricts our operations.

We are not aware of any governmental healthcare investigations of us or our executives. However, if our executives or managers were to be subject to such investigations, we could incur significant liabilities or penalties, as well as adverse publicity.

If we undertake to modify to our product, we may be required to obtain new regulatory approvals, or to cease marketing or recall the modified product until approvals are obtained.

If we were to modify our product after PMA approval, and such modification could significantly affect the product's safety or effectiveness, or constitute a major change in its intended use, design, or manufacture, we would be required to obtain a modification to the PMA. The FDA requires every manufacturer to make the determination as to whether to seek modification of a PMA; however, the FDA may review any manufacturer's decision. The FDA may not agree with our decision regarding whether new approvals are necessary. If we determine that a modification to a PMA approval is unnecessary, and the FDA disagrees with our determination and requires us to submit new PMAs for modifications to our previously-approved product, we may be required to cease marketing or to recall the modified product until we obtain approval. In that event, we may be subject to significant regulatory fines or penalties.

Further, the FDA's ongoing review of the PMA process may make it more difficult for us to modify our previously approved product, either by imposing stricter requirements as to when to initiate a new PMA submission, for a modification to a previously approved product, or by imposing more strenuous review criteria to such submissions.

If we violate applicable fraud and abuse laws, including anti-kickback laws and anti-referral laws, our business could suffer.

Numerous federal and state laws pertain to healthcare fraud and abuse, including anti-kickback laws and physician self-referral laws. Under these laws, our relationships with healthcare providers and other third-parties are subject to review. Violations of these laws are punishable by criminal and civil sanctions, including imprisonment and exclusion from participation in federal and state healthcare programs such as the Medicare, Medicaid and Veterans Administration health programs.

Healthcare fraud and abuse regulations are complex, and even minor irregularities can potentially give rise to claims that a statute or prohibition has been violated. The laws that may affect our ability to operate include:

- the federal healthcare programs' Anti-Kickback Law, which prohibits, among other

things, persons from knowingly and willfully soliciting, receiving, offering or providing remuneration, directly or indirectly, in exchange for or to induce either the referral of an individual for, or the purchase, order or recommendation of, any good or service for which payment may be made under federal healthcare programs such as the Medicare and Medicaid programs;

- federal false claims laws which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid, or other third-party payors that are false or fraudulent;

- the federal Health Insurance Portability and Accountability Act of 1996, which created federal criminal laws that prohibit executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters;

- the Federal Trade Commission Act and similar laws regulating advertisement and consumer protections; and

- foreign and U.S. state law equivalents of each of the above federal laws, such as anti-kickback and false claims laws which may apply to items or services reimbursed by any third-party payor, including commercial insurers.

Further, the Patient Protection and Affordable Care Act, as amended by the Healthcare and Education Affordability Reconciliation Act (collectively, the "PPACA"), amends the intent requirement of the federal anti-kickback and criminal healthcare fraud statutes. As such, a person or entity can now be found guilty under the PPACA even if he or it lacks actual knowledge of the statute or specific intent to violate it. In addition, under the PPACA, the government may assert that a claim resulting from a violation of the federal anti-kickback statute constitutes a false or fraudulent claim for purposes of the false claims statutes. Sanctions for violation of these anti-kickback laws include monetary fines, civil and criminal penalties, exclusion from Medicare and Medicaid programs and forfeiture of amounts collected in violation of those prohibitions. Any violations of these laws, or any action against us for violation of these laws, regardless of the outcome, could create a material adverse effect on our reputation, business, financial condition and operating results.

Any state or federal regulatory review of us, regardless of the outcome, would be costly and time-consuming. Additionally, we cannot predict the impact of any changes in the applicable laws, whether or not retroactive.

Legislative or regulatory healthcare reforms may make it more difficult and costly for us to obtain regulatory approval of our product.

The sales of our product depend in part on the availability of coverage and reimbursement from third-party payors such as government health administration authorities, private health insurers, health maintenance organizations and other healthcare-related organizations. Both the federal and state governments in the United States continue to pass new legislation and regulations designed to contain the cost of healthcare. This legislation and regulation may result in decreased reimbursement for medical devices, which may further create industry-wide pressure to reduce

the prices charged for medical devices. This could harm our ability to market our products and generate sales.

In addition, FDA regulations and guidance are often revised or reinterpreted by the FDA in ways that may significantly affect our business and our products. Any new regulations or revisions, or reinterpretations of existing regulations, may impose additional costs or lengthen the time for the review of our product. Delays in the receipt of regulatory approvals for our proposed product, or even the possible denial of regulatory approval, would have a material adverse effect on our business, financial condition and operating results.

We may be liable if we engage in the off-label promotion of our product.

Our promotional materials and training methods must comply with FDA and other applicable laws and regulations, including the prohibition of the promotion of the off-label use of our products. Healthcare providers may use our products off-label, since the FDA does not regulate a physician's choice of treatment within the practice of medicine. However, if the FDA determines that our promotional or training materials constitute promotion of an off-label use, we could be subject to regulatory or enforcement actions, including the issuance of an untitled letter, a warning letter, injunction, seizure, civil fine and criminal penalties. In addition, other federal, state or foreign enforcement authorities might act if they consider our promotional or training materials to constitute promotion of an unapproved use. Such action could result in significant fines or penalties. Although we would refrain from statements that could be considered off-label promotion of our products, the FDA or another regulatory agencies could disagree and conclude that we have engaged in off-label promotion. In addition, the off-label use of our products may increase the risk of product liability claims. Product liability claims are expensive to defend and could result in substantial damage awards against us and harm our reputation.

We face the risk of product liability claims and may not be able to maintain or obtain appropriate insurance.

The testing, manufacturing and marketing of medical devices inherently involves the risk of product liability claims. Such claims may also arise from the misuse or malfunction of, or design flaws in, our product. We may be subject to product liability claims if our products cause, or merely appear to have caused, an injury. Claims may be made by patients, healthcare providers or others selling our products. Although we will have product liability and clinical trial liability insurance that we believe will mitigate appropriate levels of risk, this insurance is subject to deductibles and coverage limitations. Our product liability insurance may not continue to be available to us on acceptable terms, and, if available at all, the coverages may not be adequate to protect us against any future product liability claims. Further, if additional products are approved for marketing, we may seek additional insurance coverage. If we are unable to obtain acceptable insurance, or otherwise protect against potential product liability claims, we will be exposed to significant liabilities. These liabilities may harm our business. A product liability claim, with respect to uninsured liabilities or for amounts in excess of insured liabilities, could result in significant costs and significant harm to our business.

We may be subject to claims against us even if the apparent injury is due to the actions of others or misuse of the product. Our customers, either on their own or following the advice of their

physicians, may use our product in a manner not described in the product's labeling and which differs from the manner in which it was used in clinical studies and approved by the FDA. Such misuse could result in liability, which could prevent or interfere with our product marketing efforts. The defense of a suit, regardless of merit, could be costly, could divert management attention, and could result in adverse publicity. Such circumstances could result in the withdrawal of, or inability to recruit, clinical trial volunteers or result in reduced acceptance of our product in the market.

Failure to obtain regulatory approval in foreign jurisdictions will prevent us from marketing our product abroad.

We may seek to market the product in foreign jurisdictions. Outside the United States, we can market a product only if we receive a marketing authorization and, in some cases, pricing approval, from the appropriate regulatory authorities. The approval procedure varies among countries and can involve additional testing, and the time required to obtain approval may differ from the time required to obtain FDA approval. The foreign regulatory approval process may include all of the risks associated with obtaining FDA approval in addition to other risks. We might not obtain foreign regulatory approvals on a timely basis, if at all. Approval by the FDA does not ensure approval by regulatory authorities in other countries, and approval by one foreign regulatory authority does not ensure approval by regulatory authorities in other foreign countries or by the FDA. We have not taken any actions to obtain foreign regulatory approvals. We may not be able to file for regulatory approvals and may not receive necessary approvals to market our products in any jurisdiction outside the United States on a timely basis, or at all.

INDEBTEDNESS

In late 2015, our CEO, Ed Damiano, advanced the Company $125.00 to open a business checking account. The advance does not accrue any interest and is payable on demand. Aside from the above-mentioned advance and certain contractual obligations with our contract manufacturers and other service providers, the Company has not taken on any debt. In addition to continuing to raise money through equity financing, in the future it will likely be necessary for the Company to raise funds through debt financing as well.

EXEMPT OFFERINGS

Since its inception in October 2016, the Company has raised a gross total of $11 MM in equity sales which amount is comprised of a $5 MM investment from Eli Lilly & Company (Series A Preferred Stock Round which closed December 31, 2015), a $5 MM investment from Novo Nordisk A/S (Series A-2 Preferred Stock round which closed September 20, 2016), and our first ~ $1 MM Regulation CF offering (Class C Common Stock which closed September 8, 2016).

Offering Date	Exemption	Security Type	Amount Sold	Use of Proceeds
Eli Lilly & Company	Private offering that was exempt from	Class A Preferred Stock	$5,000,000 for 5% of the outstanding	General business operations and

	registration under Securities Act § 4(2).		shares	continued development of the iLet
Novo Nordisk A/S	Private offering that was exempt from registration under Securities Act § 4(2).	Class A-2 Preferred Stock	$5,000,000 for 4.7% of the outstanding shares	General business operations and continued development of the iLet
Regulation Crowdfunding through Wefunder	Exempt from registration under Securities Act § 4(a)(6).	Class C Common Stock	$1,000,000 for .99% of the outstanding shares	General business operations and continued development of the iLet

TRANSACTIONS WITH RELATED PARTIES

The Company has entered into a sublease with a related party for its West Coast offices. The related party has disclosed the material terms of the sublease. The Company is not paying the related party a premium for the lease. Rather, the costs are exactly what is borne by the related party for the master lease. Additionally, prior to our formation, we incurred certain startup expenses. Related parties were compensated for pre-incorporation expenses and services in an amount not exceeding $50,000.

FINANCIAL CONDITION OF THE ISSUER

A. Overview

As a development stage medical technology company – whose only product, the iLet, has not yet achieved regulatory approval – we do not generate any revenue, nor are we likely to obtain revenue on the sale of any product until the iLet is approved for sale. Since our inception to the date of this report, we have focused on design, development, engineering and clinical testing of the iLet as well as development of strategic partnerships and corporate infrastructure to support growing operations.

B. Financial Condition of Beta Bionics

Unaudited Fiscal Picture

Fiscal year	FY 2015	FY 2016
Total assets	5,015,954	7,863,770
Cash & Cash equivalents	125	7,277,339
Account receivable	0	0
Short-term Debt	267,070	245,374

Long-term Debt	0	0
Revenues/Sales	0	0
Cost of Goods Sold	0	0
Taxes paid	0	456
Net Income	-230,547	-3,197,488

Statement Regarding Unaudited Financial Information

The unaudited financial information set forth in this report is subject to less rigorous standards than audited statements or reviewed statement prepared under the Generally Accepted Accounting Principles and, as such, are more prone to errors. Adjustments and modifications to the financial statements may be identified at a later date and time, which could result in significant differences from the information provided in this report. However, the Company's Treasurer and CFO has reviewed the financials and certified them to be true and complete in all material respects as required by Rule 201.

Net Income

From our inception in October 21, 2015 through the end of December 31, 2016, we have sustained a net loss of $3,428,035. The vast majority of our net losses are comprised of operating expenses such as salaries and benefits, consultants, general overhead and administrative expenses, leases, research and development, as well as travel costs. We expect that our operating expenses will increase significantly in 2017 and 2018 as we continue to hire additional employees and incur costs associated with building the iLet to acceptable quality standards for additional clinical trials and the additional costs related to the final PMA as well as potential CE marking and ISO certification. Given the fact that we are pre-revenue, we expect that our net losses will continue to increase at an accelerated pace based on the increased operational expenses the closer we get to commercialization.

Stock Plan

On February 5, 2016, the Company adopted its 2016 Equity Incentive Plan (the "Plan"). The Plan authorizes options to purchase up to 10,000 shares of Class B Common Stock. On May 12, 2016 the Company amended its 2016 Equity Incentive Plan to adjust the total shares available under the Plan to 100,000 shares of Class B Common Stock to reflect the Company's 10:1 stock split.

As of December 31, 2016, the Company issued 44,000 options to purchase Class B Common Stock under the Plan at exercise prices of $16.22 per share. These options all vest over four years from the grant date with a one-year cliff period. The options expire 10 years after the date of grant. As of December 31, 2016, none of the outstanding options had vested because all options issued were still within the one-year cliff period.

Liquidity and Capital Resources

As discussed elsewhere in the report, we have financed our operations through our Series A and A-2 preferred stock sale and through sale of Class C Common Stock through our Regulation CF Offering, which, in total raised a gross of $11 MM for the Company. As of December 31, 2016, our current assets consisted of cash in the amount of $7,277,339. We expect to spend $8,886,175 to continue operations through the end of 2017, which means we need to raise additional capital to meet our operating expenses through the end of 2017. Additionally, we will need to raise significant amounts of capital beyond our needs in 2017 for continued operations and to support our Pivotal Trials and regulatory efforts. The amounts that we actually spend for any specific purpose may vary significantly from our estimates and depend on a number of factors, among which are the pace of progress of our development efforts, actual needs with respect to product testing, research and development, market conditions, as well as any legal or regulatory changes.

Our cash and cash equivalents are held for working capital purposes. We do not enter into investments for trading or speculative purposes. Our policy is to invest any cash in excess of our immediate requirements in investments designed to preserve capital and provide liquidity. Accordingly, our cash and cash equivalents are invested exclusively in demand deposit accounts and money market funds that are currently providing only a minimal return.

Inability to remain a going-concern without additional capital
The Company does not currently have enough cash on hand to complete the commercialization process for the iLet. Our ability to continue as a going concern for the next twelve months and beyond is dependent upon our ability to raise additional capital to fund our operations through either equity or debt financing. Many successive rounds of financing may be needed to achieve the Company's long-term goal. If we fail to raise additional capital sufficient to cover our operating expenses, our business will not survive. Additionally, we would be in material breach of the terms of the licensing agreements with BU if we are unable to raise sufficient additional capital, which may result in BU exercising its right to revoke the Company's rights to critical intellectual property.

Even If We Achieve Regulatory Approval, Our Public Benefit Corporate Structure Deemphasizes Shareholder Return and Emphasizes the Delivery of a Public Benefit to the T1D Community

We underscore and emphasize that even if the Company is financially successful, our corporate structure as a Massachusetts public benefit corporation and a B Lab certified B Corporation requires our management team and Board of Directors to make decisions that balance our responsibility to you and other shareholders with our obligation to Company's public benefit mission. In short, our interest in making money for you and other shareholders will not supersede the interests of the T1D community.

Assuming We Can Obtain Approval and Raise Enough Money to "Go To Market", Company Revenue on Sales Is a Huge Guess in a Rapidly Evolving Payer Market – It Is Not Possible To Reliably Predict Any Reimbursement Model at this Stage.

The Company cannot reliably estimate how much it can expect in revenue on the sale of the iLet and related consumables. The earliest that we expect to generate revenue from the sale of the iLet in the insulin-only configuration is in the mid 2019. However, that estimate can easily be

delayed for multiple reasons, such as failure to raise enough funds to conduct or complete the pivotal trials, lack of funds to operate the Company, lack of volunteer subjects to compete the pivotal trial, or inability to obtain regulatory approval.

Even if the Company is successful in meeting all of these challenges, a model for reimbursement of an autonomous glucose control system does not yet exist. The only analogous reimbursement structure is the insulin pump and CGM reimbursement model. As recently as May 2016, at least one payer has disclosed that its covered patients 18 years of age and over will no longer be permitted to choose their own insulin pump supplier due to an exclusive relationship between the payer and a pump manufacturer. We are working to understand exactly the nature of this exclusive relationship, but given this recent development, it is conceivable that payers may develop exclusive anti-competitive arrangements with manufacturers of autonomous or partially autonomous glucose control systems, which may operate to exclude the Company from ever obtaining third party reimbursement. Such a result may be fatal to the Company's viability even after achieving regulatory approval.

REGULATORY INFORMATION

The Company has not previously failed to comply with the requirements of Regulation Crowdfunding.

OTHER MATERIAL INFORMATION

Any other material information that may be necessary to make the required statements, in the light of the circumstances under which they are made, not misleading.

In April 2017, the Company received a demand letter under Massachusetts General Laws Chapter 93A, Section 9 ("Chapter 93A") from an attorney representing Kirk Ramey, a former research scientist who worked in Ed Damiano's lab at Boston University ("BU") from 2013 to 2015 threating to sue the Company as well as Ed Damiano, Firas El-Khatib and BU. Mr. Ramey claims that he was promised an equity stake in Beta Bionics in exchange for his work at the BU lab on the bionic pancreas related technology. Mr. Ramey also claims that the Company, Firas El-Khatib, Ed Damiano and BU have interfered with his rights as an inventor on various patents and thereby deprived him of his rights to certain royalties. In addition to claims under Chapter 93A, Mr. Ramey is threatening to bring claims for alleged violations of the breach of fiduciary duty, breach of contract, breach of the covenant of good faith and fair dealing, promissory estoppel, negligent and fraudulent misrepresentation, tortious interference, as well as a request for a declaratory judgment confirming Mr. Ramey's alleged equity interest in the Company. The Company denies that it or any of its officers or employees ever promised Mr. Ramey any equity in Beta Bionics in exchange for the work Mr. Ramey performed at BU or engaged in any of the other alleged unlawful activities, including, without limitation, any alleged interference with Mr. Ramey's rights to royalties as an inventor, if any. The Company is prepared to vigorously defend itself and its officers and employees in the threatened litigation. Even if we are to ultimately prevail, the threatened litigation could burden us with substantial unanticipated costs. In addition, the threatened litigation could result in significant demands on the time and attention of our

management team, distracting them from the pursuit of other Company business. In addition, the uncertainties associated with litigation could have a material adverse effect on our ability to raise the funds necessary to continue our clinical trials, continue our internal research programs, or enter into strategic partnerships that would help us bring the iLet to market.